



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FPAA810PCT	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/IN2005/000336	International filing date (day/month/year) 10.10.2005	Priority date (day/month/year) 22.06.2005
International Patent Classification (IPC) or national classification and IPC INV. A23L1/236		
Applicant Alembic Limited		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 2007-04-20	Date of completion of this report 15.10.2007	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Vermeulen, Stéphane Telephone No. +49 89 2399-7520 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IN2005/000336

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-10 as originally filed

Claims, Numbers

1-13 received on 23.04.2007 with letter of 20.04.2007

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☒ the claims, Nos. 1,7,11
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IN2005/000336

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>3,4,9-13</u>
	No: Claims	<u>1,2,5-8</u>
Inventive step (IS)	Yes: Claims	<u>3,4,9-13</u>
	No: Claims	<u>1,2,5-8</u>
Industrial applicability (IA)	Yes: Claims	<u>1-13</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I

Basis of the report

1. The amendments filed with the letter dated 20.04.2007 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
 - a.) bulk density from about 0.05 to about 0.25 g/cc (cf. claims 1, 7, 11)
 - b.) bulk density below 0.25 g/cc (cf. claims 1, 7, 11)
2. No basis can be found for the above mentioned values in the originally filed application. Although Table 7 discloses a granule bulk density of 0.25 g/cc for one example, namely example 7, this value cannot be generalized, because it is specifically linked to the parameters characterizing the given example (i.e. bulk density of the starting core material, type of core material used, type of granulation liquid used, etc...).
3. The only general basis for the granule bulk density in the original application is found in original claim 3. Said claim provides a basis for a bulk density in the range of 0.05 to 0.3 g/cc.
4. With respect to the bulk density of the low density bulking agent, the original application provides a general basis for a bulk density of below 0.3 g/cc (cf. page 3, line 8).
5. Accordingly, the present examination report has been drawn up for claims 1, 7 and 11 with the assumption that the non-allowable amendments are corrected as suggested in above points 3 and 4.

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:
D1: GB-A-1 543 167 (TATE & LYLE LTD) 28 March 1979
D2: US-B1-6 423 358 (BARNDT RICHARD L ET AL) 23 July 2002
D3: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 05, 14 September 2000 & JP 2000 037169 A (MATSUTANI CHEM IND LTD), 8 February 2000
D4: PATENT ABSTRACTS OF JAPAN vol. 2002, no. 09, 4 September 2002 & JP 2002 136270 A (SANEI GEN FFI INC), 14 May 2002
D5: EP-A-0 545 890 (RAFFINERIE TIRLEMONTTOISE) 9 June 1993
D6: US 2004/258822 A1 (LIAO SHYHYUAN ET AL) 23 December 2004
D7: WO 99/30577 A (THE NUTRASWEET COMPANY) 24 June 1999
2. The composition and method of preparation according to independent claims 1 and 7 lack novelty over D2 (Article 33(2) PCT). D2 (cf. column 2, lines 62-67) discloses a process wherein sucralose is co-dried or spray-dried on an inulin carrier (low density bulking agent) to produce a tabletop product with densities ranging from 0.1 g/cc to 0.8 g/cc. Hence, the bulk densities defined in present claim 1 are anticipated by D2. All process steps defined in present 7 are furthermore inherently anticipated by the process referred to in D2. The process referred to in D2 implicitly comprises a wet granulation step, which takes place when the sucralose solution is spray-dried on the inulin carrier in fluidized bed. A similar process can also be found in D3 (cf. abstract and paragraph [0023]).
3. The additional features defined in the dependent claims 2, 5, 6 and 8 are also anticipated by D2. Reference is made to column 2 (lines 60-62), column 2 (line 63), column 3 (lines 11-14).
4. The subject-matter of claims 3, 4, 9, 10, 11, 12 and 13 meets the requirements of novelty and inventive step (Art. 33(2)(3) PCT). None of the prior art documents discloses the preparation of a granular sucralose having a bulk density as low as

defined in the claims, by means of a wet granulation process using a rapid mixer granulator or a planetary mixer. The state of the art rather suggests fluidized bed granulation or spray-drying (cf. D1, D2, D3), preferably with simultaneous CO₂ injection (cf. D4, D5) in order to achieve very low bulk densities. D6 does not deal with a low density product. D7 is silent about product density and it does not suggest wet granulation. The experimental data provided in the present application (cf. Table 7) show that it is possible to achieve very low bulk densities by wet granulation in rapid mixer granulators or planetary mixers, provided that the core material used, ie. the bulking agent, has a very low initial bulk density. This was not rendered obvious by any of the cited prior art documents.

5. The subject-matter of claims 1-13 is considered to be industrially applicable and accordingly meets the requirements of Art.33(4) PCT.

Re Item VIII

Certain observations on the international application

Claim 7 defines a method for the preparation of a granular composition having a specific bulk density. The granular composition is furthermore defined in that one of its constituents, namely a bulking agent, should have a specific bulk density (within the granular composition). From the description and the examples, however, it appears that the essential feature is not the bulk density of the bulking agent in the final product, but rather the bulk density of the bulking agent prior to the granulation step. In step II of claim 7 the bulk density of the bulking agent however is not defined. The same applies to claim 1, which refers to a wet granulation process. Hence, claim 7 and claim 1 do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.